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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/068,507 07/15/98 EIJSINK

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EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/068,507

Applicant(s)

Eijsink et al.

Examiner

Elizabeth Slobodyansky

Group Art Unit

1652



☒ Responsive to communication(s) filed on Jul 2, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 44-68 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 44-68 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The amendment filed July 2, 2001 amending the specification to correct clerical errors, amending claims 44-46, 65 and 66 and adding claims 67 and 68 has been entered.

Claims 44-68 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 44-65, 67 and 68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is the written description rejection that has been explained in the Office action mailed January 2, 2001 as applied to claims 44-65. New claims 67 and 68 are included in this rejection because they are drawn to a gene expressing system and a

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method of use thereof, respectively, comprising the same elements against which the previous rejection is made.

Claim 44, with dependent claims 46, 48-62, claims 64, 65, 67 and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a gene expression system comprising a promoter inducible by the IF gene expression product, an IF gene, a SakK gene and a SakR gene, a kit comprising it and a method of use thereof, does not reasonably provide enablement for an expression system comprising functional analogs of said elements and a kit and a method of use thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 44-65, 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44-65, 67 and 68 recite functional analogues. There is no art-accepted definition of said term. The claims further define "functional analogue" as "identical or similar to peptides that are naturally produced by lactic acid bacteria ...". The term

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"similar" is indefinite since it is not clear what structures Applicants intend to cover by the recitation of "similar".

Claim 64 is confusing because it reads on a vector comprising a SakR gene and a host cell comprising the same gene.

Claim Rejections - 35 USC § 102

Claims 44-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Diep et al. (1994).

This rejection that has been explained in the Office action mailed January 2, 2001.

Claims 44-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Tichaczek et al.

This rejection that has been explained in the Office action mailed January 2, 2001.

Claims 44-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Axelsson et al.

This rejection that has been explained in the Office action mailed January 2, 2001.

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Claims 44-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Venema et al. (1994).

This rejection that has been explained in the Office action mailed January 2, 2001.

Response to Arguments

Applicant's arguments filed July 2, 2001 have been fully considered but they are not persuasive.

Regarding the written description rejection Applicants argue that "the claims do not encompass elements not discovered" (page 13). The claims were rejected because IF, K and R are not sufficiently described. The point of the rejection is that absent the description of these genes by a specific structure they lack sufficient written description. In particular because the specification teaches that "[i]n the present invention references to the group IF, K and R (or analogs thereof) should be interpreted as a reference to IF, K, R and such a possible extra gene if it would appear to exist" (page 21, lines 17-20 and the sentence bridging pages 10 and 11, emphasis added). Therefore, it is unclear whether reference to IF, K, R encompasses the respective sequences or in addition an extra gene. The specification discloses that "[i]t is possible that a product of a hitherto unknown gene is also required" (ibid). The examiner interpreted "a hitherto unknown gene" as a gene "not yet discovered at the time the application was filed".

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Applicants go on to assert that the reference to a structure is not needed because they claim "a gene expression system, rather than isolated nucleic acids per se" and because "applicants are claiming functional analogues rather than structural analogues" (page 15). This is not persuasive because "a gene expression system" comprises nucleic acids. Further, function is determined by structure and every chemical compound has its own structure while function may be imparted by many structures and shared by structurally different compounds. Therefore, the description by function only does not provide a sufficient written description of a compound.

With regard to the enablement Applicants argue that "the repetition of the experiments described in Examples 1 and 2 of the specification led to the identification of a similar mechanism in *L. plantarum* C11 (page 18). This does not contradict to the rejection. The rejection is made of functional analogs of the genes of unknown structure. Structurally homologous genes from the same bacterial genus, *Lactobacillus*, are enabled. However, the claims are not directed to structurally homologous genes from *Lactobacillus*.

With regard to the 112, 2nd paragraph, rejection, Applicants argue that "[t]he specification of pages 12-14 clearly teaches the skilled artisan that functional analogues of SakK and SakR can be easily recognized by sequence homology" (page 23). This is not persuasive because first, the claims are not reciting any sequence

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homology and, second, the careful reading of pages 12-14 does not reveal any reference to sequence homology.

With regard to the 102 rejections, Applicants argue that "neither Tichaczek et al., Axelsson et al., or Venema et al, show, state, or suggest any of the following: (1) the presence of a regulatory mechanism, (2) the character of such mechanism, (3) the presence or character of an "inducing substance" (page 26). This is not persuasive because all the above characteristics are inherent to the system. The claim 68 that is drawn to a method of use of said system is not anticipated.

In conclusion, Applicant's arguments do not clearly point out the patentable novelty which they think the claims present in view of the state of the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

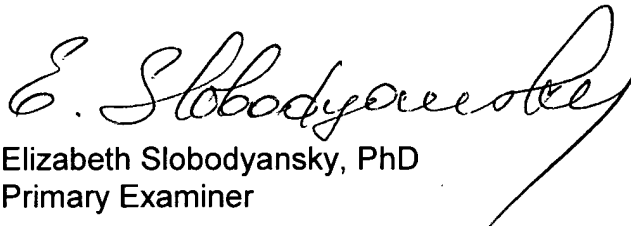
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

September 28, 2001